ONETOUCH®

Verio™

Blood Glucose Monitoring System

USER GUIDE

Owner's Booklet refers to User Guide

AW 06683701A
Rev. date: 02/2010
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LifeScan self-test blood glucose monitoring devices conform to the following EU Directives:

IVDD (98/79/EC):

CE 0344 Blood Glucose Meter, Test Strips, and Control Solution

MDD (93/42/EEC):

CE 0120 Lancets

CE Blood Sampler

Customer Service
Call Customer Service: 1800-LifeScan
Customer Service is available from 8:00 AM to 6:00 PM, Monday - Friday.
www.OneTouch.com.au

If you have any questions about the use of any LifeScan product, contact Customer Service: 1800-LifeScan.
Customer Service is available from 8:00 AM to 6:00 PM, Monday - Friday.
If you cannot reach Customer Service, contact your health care professional for advice.

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Milpitas, CA 95035 USA

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The system described herein is covered by one or more of the following U.S. patents: 6,179,979, 6,193,873, 6,284,125, 6,475,372, 6,716,577, 6,749,887, 6,797,150, 6,863,801, 6,872,298, 7,045,046, and 7,498,132. Use of the monitoring device included herein is protected under one or more of the following U.S. patents: 6,413,410, 6,890,421. Purchase of this device does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch® Verio™ Test Strip. No test strip supplier other than LifeScan is authorised to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

Symbols

- Cautions and Warnings. Refer to the User Guide and inserts that came with your system for safety-related information.
- Direct current
- Backlight
- Low Battery
- Do not reuse
- SN Serial number
- Upper storage temperature limitation
- Expiration Date
- Consult Instructions for Use
- On/Off
- IVD In Vitro Diagnostic Medical Device
- Manufacturer
- Σ n Contains sufficient for <n> tests
- LOT Lot Number
- STERILE R Sterilised by irradiation

Before you begin
Before using this product to test your blood glucose, carefully read this User Guide and the inserts that come with the OneTouch® Verio™ Test Strips and OneTouch® Verio™ Control Solution.

Test principle
Glucose in the blood sample mixes with special chemicals in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current, calculates your blood glucose level, displays the result, and stores it in its memory.

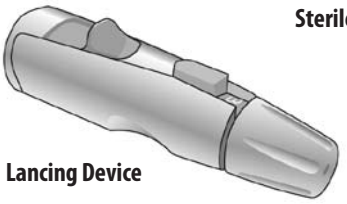
Intended use
The OneTouch® Verio™ Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The OneTouch® Verio™ System is intended for self-testing outside the body (*in vitro* diagnostic use) by people with diabetes at home and by health care professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control.

The OneTouch® Verio™ Blood Glucose Monitoring System should not be used for:
• The diagnosis of diabetes.
• Testing newborns.
• Patients within 24 hours of receiving a D-xylose absorption test as it may cause inaccurately high results.

The OneTouch® Verio™ Blood Glucose Monitoring System

INCLUDED WITH YOUR KIT:

OneTouch® Verio™ Meter (batteries included)



Lancing Device

Sterile Lancet

Carrying Case

OneTouch® Verio™ Test Strips

If another type of lancing device was included, see the separate instructions for that lancing device.

AVAILABLE SEPARATELY:

Clear Cap

OneTouch® Verio™ Control Solution

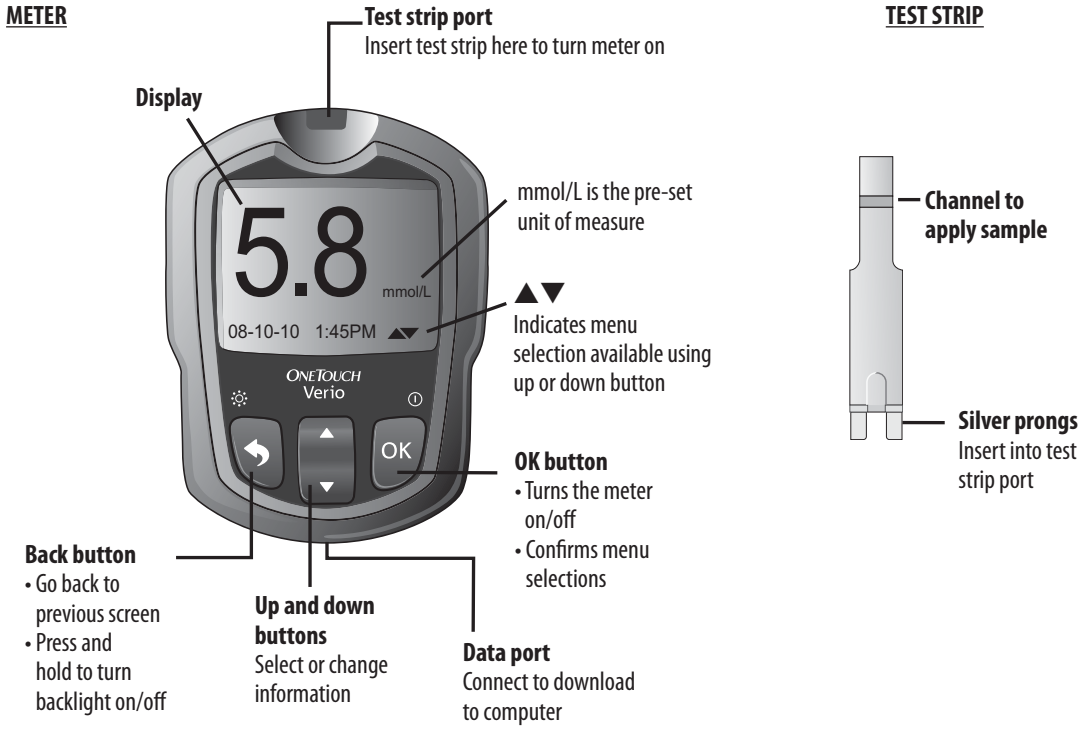
For availability of control solution, contact Customer Service: 1800-LifeScan or contact www.OneTouch.com.au or ask for control solution where you obtain your test strips.

For availability of the Clear Cap, contact Customer Service: 1800-LifeScan or contact www.OneTouch.com.au.

⚠ WARNING: Keep the meter and testing supplies away from young children. Small items such as the battery door, batteries, test strips, lancets, protective covers on the lancets, and control solution vial cap are choking hazards. Do Not ingest or swallow any items.

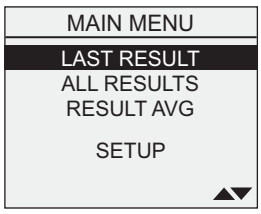
1 Setting up your system

The OneTouch® Verio™ Blood Glucose Meter and Test Strips



Turning your meter on

Press and hold OK until the black start-up screen appears. Once the black start-up screen is displayed, release OK. After the black start-up screen, the MAIN MENU is displayed.



⚠ **CAUTION:** If you see any light areas within the black start-up screen, there may be a problem with the meter. Contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.

Using the display backlight

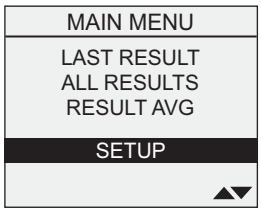
When the meter is on, press and hold ↩ any time you want to turn the display backlight on or off.

Setting the meter language, audio, date and time

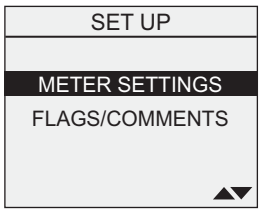
Before using your meter for the first time, you should check these settings. When using the meter for the first time, you will automatically start at the LANGUAGE screen (go to Step 2).

❶ Go to the SETUP screen

From the MAIN MENU, press ▲ or ▼ to highlight SETUP and press OK.



Then, press ▲ or ▼ to select METER SETTINGS and press OK.

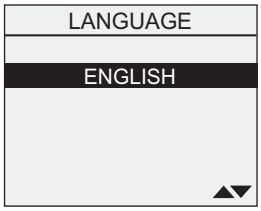


❷ Choose a language

Press ▲ or ▼ to highlight the language you want and press OK.

Pressing OK after making your selection confirms each setting and takes you to the next screen.

When setting up your meter, you can press ↩ to return to the previous screen to adjust a setting.

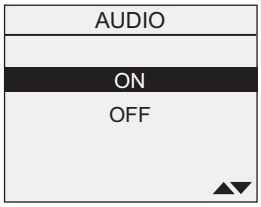


❸ Set the audio function

You can set your meter to beep to notify you during certain meter operations.
With the audio function on, you will hear:

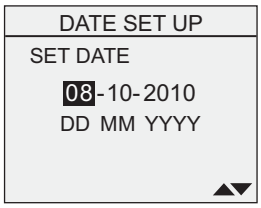
- One beep when it is time to apply your sample or when a test result is displayed, and
- Two beeps to alert you to a problem with the meter or test procedure.

Press ▲ or ▼ to highlight ON or OFF and press OK.



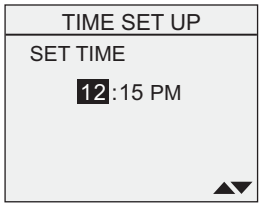
❹ Set the date

In the DATE SET UP screen, press ▲ or ▼ to change the first value and press OK.
Repeat these steps to set the second value, then the year.



❺ Set the time of day

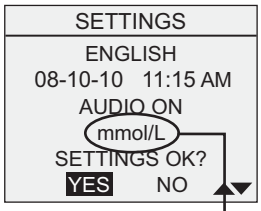
Press ▲ or ▼ to set the hour and press OK. Repeat this step to set the minutes.
Press ▲ or ▼ to set AM or PM and press OK.



❻ Confirm your settings

If your settings are correct, make sure that YES is highlighted, then press OK to save them and return to the MAIN MENU.

If you need to change a setting, press ▲ or ▼ to highlight NO and press OK. You will return to the LANGUAGE screen.



⚠ WARNING: The unit of measure mmol/L should be displayed here. If your display shows mg/dL rather than mmol/L, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

Turning your meter off after setup

There are two ways to turn your meter off:

- Press and hold OK for one second.

Or,

- Your meter will turn off by itself if left alone for two minutes.

2 Testing your blood glucose

Testing with a fingertip sample

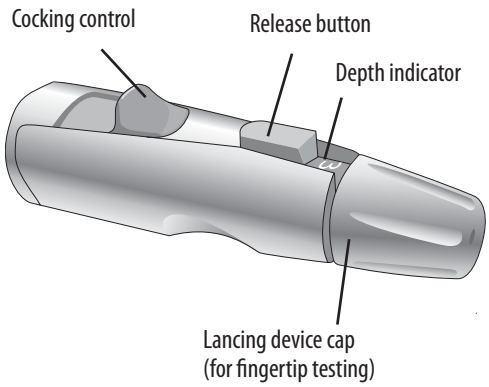
Preparing for a test

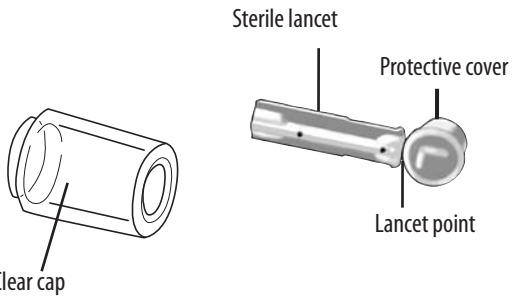
Have these things ready when you test:
OneTouch® Verio™ Meter
OneTouch® Verio™ Test Strips
Lancing device
Sterile lancets

- Use only OneTouch® Verio™ Test Strips.
- When you first open a vial of test strips, record the discard date on the label. Refer to the test strip insert or vial label for instructions on determining the discard date.
- Unlike some blood glucose meters, no separate step to code your OneTouch® Verio™ System is required.
- Make sure your meter and test strips are about the same temperature before you test.
- **Do Not** open the test strip vial until you are ready to test. Use the test strip **immediately** after removing it from the vial.
- **Do Not** test if there is condensation (water build-up) on your meter. Move your meter and test strips to a cool, dry spot and wait for the meter surface to dry before testing.
- After removing a test strip from the vial, **immediately** close the lid tightly to avoid contamination and damage.
- Store unused test strips only in their original vial.
- After performing a test, **Do Not** put the used test strip back in the vial.
- **Do Not** re-use a test strip that had blood or control solution applied to it. Otherwise, you may get an inaccurate low result. Test strips are for single use only.
- With clean, dry hands, you may touch the test strip anywhere on its surface. **Do Not** bend, cut or modify the test strips in any way.

⚠ CAUTION:
- **Do Not** use your test strips if your vial is damaged or left open to air. This could lead to error messages or inaccurate results. If you find that the vial is uncapped or damaged in any way before you begin using a new vial of test strips, contact Customer Service at 1800-LifeScan immediately. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.
- This meter meets all applicable standards, but some cell phones may interfere with the proper operation of your meter if next to the meter during testing.
- If you cannot test due to a problem with your testing supplies, contact your health care professional. Failure to test could delay treatment decisions and lead to a serious medical condition.
- The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.
- **Do Not** use test strips after the expiration date (printed on the vial) or the discard date, whichever comes first, or your results may be inaccurate.

Lancing Device



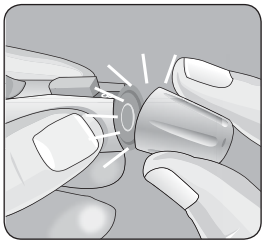

Sterile lancet
Protective cover
Lancet point
Clear cap
(for forearm and palm testing)
See *Testing with a forearm or palm sample* in Section 2.

⚠ **CAUTION:** To reduce the chance of infection:

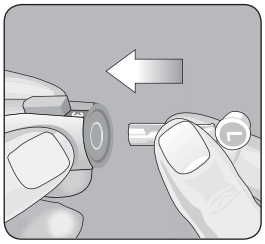
- Make sure to wash the sample site with soap and warm water, rinse and dry before sampling.
- Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet each time you test.
- Always keep your meter and lancing device clean (see *Caring for your system* in Section 6).

Getting a blood sample from the fingertip

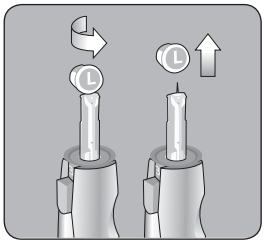
Before testing, wash your hands thoroughly with warm, soapy water. Rinse and dry.



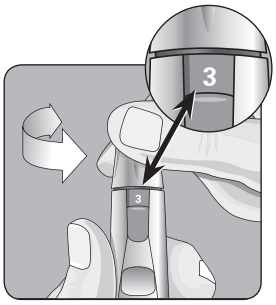
❶ Snap off the lancing device cap



❷ Insert a sterile lancet
Firmly push the lancet into the holder.

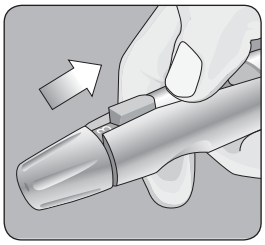


Twist off the protective cover and save it for later use. Replace the lancing device cap.



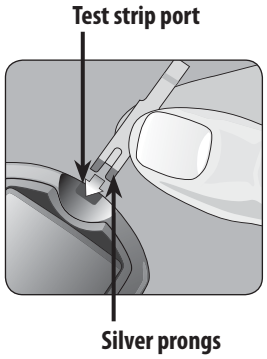
❸ Adjust the depth setting
Twist the lancing device cap until the desired setting appears. Smaller numbers are for shallower punctures, which may be less painful.

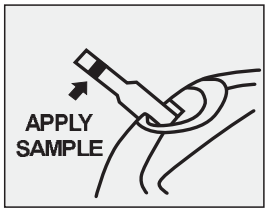
Shallower punctures work for children and most adults. Deeper punctures work well for people with thick or callused skin.



❹ Cock the lancing device
Slide the cocking control back until it clicks. If it does not click, that's okay. It may have been cocked when you inserted the lancet.

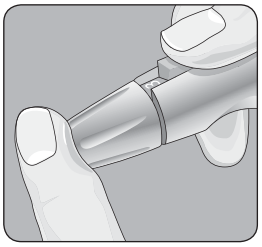
❺ Insert a test strip to turn the meter on
Insert the test strip into the test strip port with the gold side of the strip and the two silver prongs facing you. No separate step to code the meter is required.





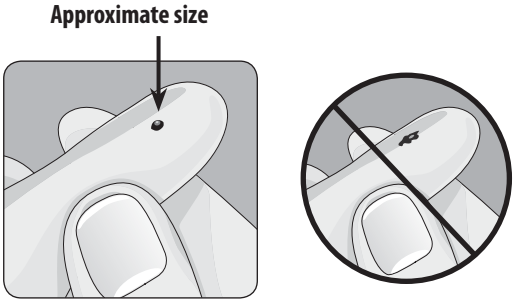
When the APPLY SAMPLE screen appears on the display, you can apply your blood sample.

❻ Lance your finger
Hold the lancing device firmly against the side of your finger. Press the release button.



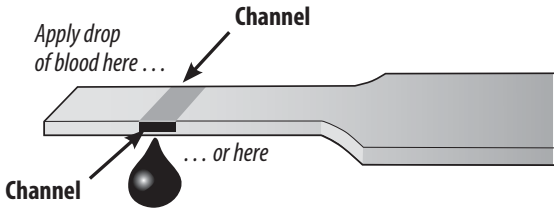
❼ Get a round drop of blood
Gently squeeze your finger until you get a round drop of blood.

If the blood smears or runs, **Do Not** use that sample. Otherwise, you may get an inaccurate low result. Wipe the area and gently squeeze another drop of blood or puncture a new site.



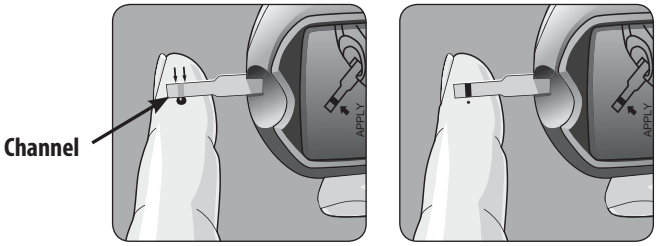
Applying blood and reading results

❶ Apply the sample to the test strip
You can apply blood to either side of the test strip. Apply your sample to the opening of the channel.



Holding the meter at a slight angle, guide the channel to the blood drop.

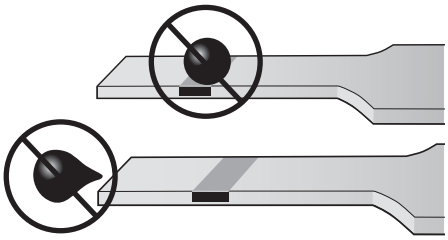
When it touches your sample, the test strip wicks blood into the channel.



❷ Wait for the channel to fill completely
The blood drop will be drawn into the narrow channel. The channel should fill completely.
The channel turns red and the meter counts down from 5 to 1.

Blood should **not** be applied on the top of the test strip or to the top edge of the test strip.

- **Do Not** smear or scrape the sample with the test strip.
- **Do Not** press the test strip too firmly against the puncture site or the channel may be blocked from filling properly.
- **Do Not** apply more blood to the test strip after you have moved the drop of blood away.
- **Do Not** move the test strip in the meter during a test.
- **Do Not** remove the test strip until the result is displayed.



❸ Read your result on the meter
Your blood glucose level appears on the display, along with the unit of measure, and the date and time of the test.

(Example)

If mmol/L does not appear with the test result, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.

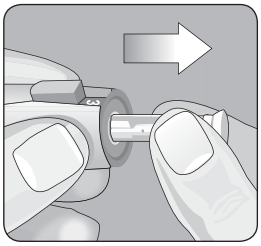
⚠ **CAUTION:** If the words **CONTROL SOLUTION** appear on the screen, repeat the test with a new test strip. If the problem persists, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.

After getting a result
Once you have your result, you may:
- Attach meal flags or comments to this result, see Section 3, Attaching meal flags or comments to your test results.

Or,
- Review your meter memory by pressing OK, see Section 4, Reviewing past results and averages.

Or,
- Turn the meter off by removing the test strip.

Removing the used lancet
Remove the lancing device cap.
Place the lancet protective cover on a hard surface and push the lancet tip into the cover.
Remove the lancet and place it in a container for sharp objects.
Replace the lancing device cap.



Disposing of the used lancet and test strip
Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your health care professional's recommendations or your local regulations for proper disposal.

Interpreting unexpected test results

Refer to the following cautions whenever your test results are higher or lower than what you expect.

⚠ **CAUTION:**

Low glucose results

If your test result is below 3.8 mmol/L or is shown as LOW GLUCOSE, it may mean hypoglycaemia (low blood glucose). This may require immediate treatment according to your health care professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.

Dehydration and low glucose results

You may get false low glucose results if you are severely dehydrated. If you think you are severely dehydrated, contact your health care professional immediately.

High glucose results

If your test result is above 10.0 mmol/L, it may mean hyperglycaemia (high blood glucose) and you should consider re-testing. Talk to your health care professional if you are concerned about hyperglycaemia.

HIGH GLUCOSE is displayed when your blood glucose level is over 33.3 mmol/L. You may have severe hyperglycaemia (very high blood glucose). Re-test your blood glucose. If the result is HIGH GLUCOSE again, this indicates a severe problem with your blood glucose control. Obtain and follow instructions from your health care professional immediately.

Repeated unexpected glucose results

If you continue to get unexpected results, check your system with control solution. See Section 5, Control solution testing.

If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this User Guide, call your health care professional. Never ignore symptoms or make significant changes to your diabetes management program without speaking to your health care professional.

Unusual red blood cell count

A haematocrit (percentage of your blood that is red blood cells) that is either very high (above 60%) or very low (below 20%) can cause false results.

Testing with a forearm or palm sample

The OneTouch® Verio™ System lets you test with a blood sample from your fingertip, forearm or palm. At times, results obtained at the forearm or palm may be different from a fingertip measurement. Talk to your health care professional before you begin using your forearm or palm for sampling.

If you are testing:	**Use blood sample from your:**
Routinely before meals Prior to or more than two hours after: • a meal • a rapid-acting insulin injection or insulin pump bolus • exercise	**Fingertip, forearm, or palm**
When your blood glucose is changing rapidly, such as: • within two hours after a meal • within two hours after a rapid-acting insulin injection or insulin pump bolus, or • during or within two hours after exercise When you are concerned about the possibility of hypoglycaemia (low blood sugar) When the forearm or palm results do not agree with the way you feel, during illness or during times of stress	**Fingertip**

⚠ **CAUTION:**

Do Not test on your forearm or palm when:

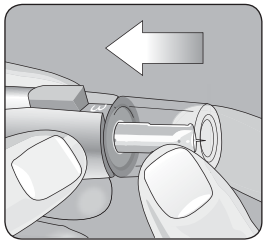
- You think your blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or pump bolus. Testing with a fingertip sample may identify hypoglycaemia or an insulin reaction sooner than testing with a forearm or palm sample.
- It has been less than two hours after a meal, a rapid-acting insulin injection or pump bolus, physical exercise, or you think your blood glucose level is changing rapidly.
- You are concerned about the possibility of hypoglycaemia or an insulin reaction, such as when driving a car. This is especially important if you suffer from hypoglycaemia unawareness (lack of symptoms to indicate an insulin reaction).
- Remember: Consult your health care professional before using your forearm or palm for testing.

Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.

If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your health care professional.

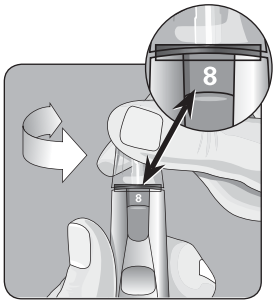
Getting a blood sample

Getting a blood sample from your forearm or palm is different than getting a sample from your fingertips. Follow these instructions to get a sufficient blood drop for testing.



❶ Insert a lancet and snap on clear cap

Carefully insert a new, sterile lancet.
Snap on the clear cap.



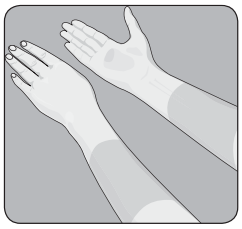
❷ Adjust the depth setting

You may need a deeper setting to get a sufficient sample for testing.
Twist the cap to increase the depth.
Be sure to cock the lancing device.

❸ Choose a sample site

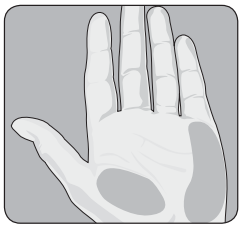
Before testing, wash your hands and forearm (if applicable) thoroughly with warm, soapy water. Rinse and dry.

Choose a fleshy spot away from bone, veins and hair. Gently massage or apply warmth to the site to increase blood flow.



Forearm

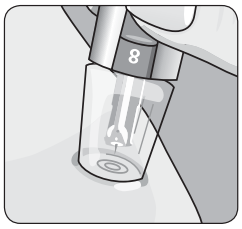
Select a fleshy spot with no visible veins and avoid deep lines which may cause your blood sample to smear.



Palm

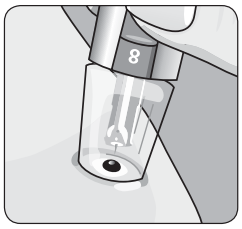
❹ Lance your forearm or palm

- Firmly press and hold the lancing device against the sample site.
- Looking through the clear cap, wait until you see the sample site change colour as blood collects under the skin. This lets you know that there is enough blood to obtain a sufficient sample for testing.
- Press the release button while continuing to apply pressure.



Forearm or Palm

- Hold the lancing device firmly against your skin until a round drop of blood forms under the cap. You may need to wait a little longer to get a large enough drop of blood from the forearm or palm.
- **Do Not** squeeze the site excessively.



Forearm or Palm

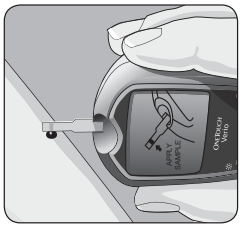
❺ Remove the lancing device

Carefully lift the lancing device away from your skin without smearing the sample.
If your sample runs or spreads because of hair on the forearm or a line in your palm, sample again in another area.

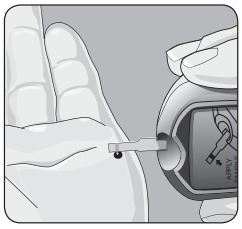
❻ Apply the sample to the test strip

Keep your forearm or palm steady and use your other hand to bring the side of the test strip channel to the drop of blood.

- See *Testing with a fingertip sample* in Section 2, for more information on applying the blood sample to the test strip.
- See *Interpreting unexpected test results* in Section 2, for more information on unexpected test results.



Forearm



Palm

3 Attaching meal flags or comments to your test results

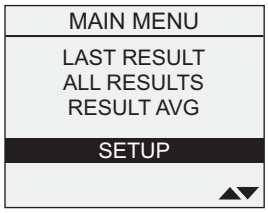
Your OneTouch® Verio™ Meter allows you to attach notes to any blood glucose result. There are two kinds of notes and different reasons to use them.

Note Type	Recommendation	Benefit
Meal Flag	Add a meal flag to every blood glucose result.	Allows you to link the effects of food to your blood glucose results. Provides you with separate averages for before-meal and after-meal tests.
Comment	Select an appropriate comment whenever you test under conditions that you or your health care professional feel are worth noting.	Helps track possible reasons for test results.

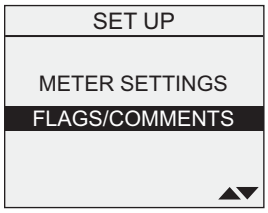
We suggest you talk to your health care professional to see how meal flags and comments may help you manage your diabetes.

Turning the meal flags/comments feature on and off

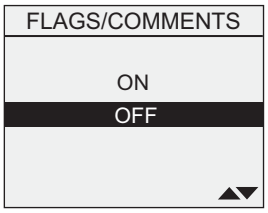
Before using your meter for the first time, you should check this setting.



1 From the MAIN MENU, press ▲ or ▼ to select SETUP and press OK



2 From the SETUP screen, select FLAGS/COMMENTS and press OK

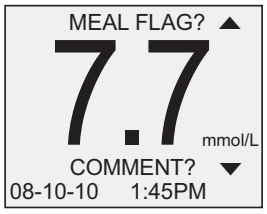


3 Press ▲ or ▼ to highlight ON or OFF and press OK

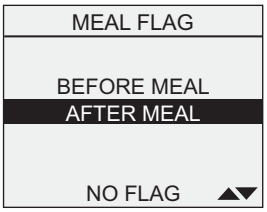
Add or change a meal flag

Meal flags and comments can be added right after you get a test result. You can also change meal flags and comments when reviewing past results.

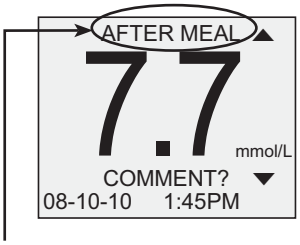
After testing, your blood glucose result is displayed and ▲ appears to the right of MEAL FLAG? on top of the screen.



1 Press ▲ to display the MEAL FLAG screen



2 Press ▲ or ▼ to highlight BEFORE MEAL or AFTER MEAL and press OK



Your meal flag will appear here

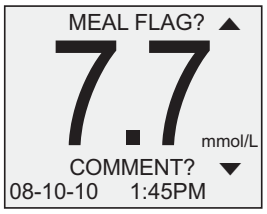
❸ To change or remove a meal flag attached to a past result, highlight the individual result (see Section 4, Reviewing past results and averages)

The result screen will be displayed. Follow steps 1 and 2 to change the meal flag. To remove a meal flag, highlight NO FLAG and press OK.

Add or change a comment

When a glucose test result is displayed after a test, ▼ appears to the right of COMMENT? at the bottom of the screen.

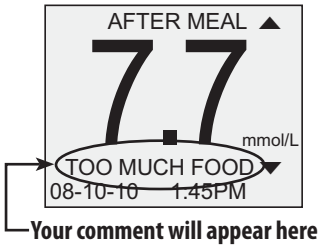
❶ Press ▼ to display the comment screen



❷ Press ▲ or ▼ to highlight the desired COMMENT and press OK

Available comments:

NO COMMENT	**STRESS**
NOT ENOUGH FOOD	**ILLNESS**
TOO MUCH FOOD	**FEEL HYPO**
MILD EXERCISE	**MENSES (period)**
HARD EXERCISE	**VACATION**
MEDICATION	**OTHER**



Your comment will appear here

❸ To change or remove a comment attached to a past result, highlight the individual result (see Section 4, Reviewing past results and averages)

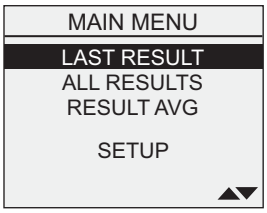
The result screen will be displayed. Follow steps 1 and 2 to change the comment. To remove a previously entered comment, highlight NO COMMENT and press OK.

4 Reviewing past results and averages

Reviewing past results and averages

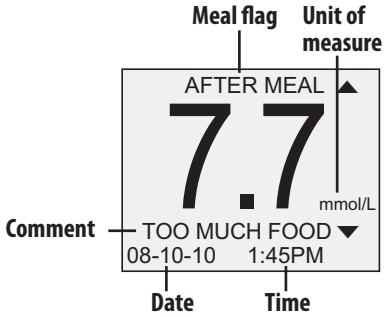
If your meter is off, press and hold OK until the black start-up screen appears. Once the black start-up screen is displayed, release OK.
If you have just completed a test, press OK to get to the MAIN MENU from the result screen.

From the MAIN MENU, choose:
- LAST RESULT to view your most recent result
- ALL RESULTS to review up to 500 of your most recent results
- RESULT AVG to view averages for:
  - all test results
  - all before-meal results
  - all after-meal results



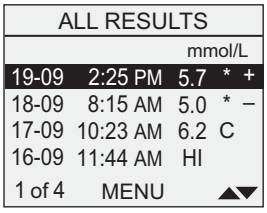
Press ▲ or ▼ to highlight your selection and press OK.

Last result
The meter will display your most recent result.
Press ↩ to return to the MAIN MENU.



All results
The meter will display four results at a time, starting with the most recent. The following symbols may also appear:

HI	if the result was above 33.3 mmol/L
LO	if the result was below 1.1 mmol/L
*****	if a comment was added to the result
C	if the result is from a control solution test (see Section 5, Control solution testing)
–	if the result is flagged BEFORE MEAL
+	if the result is flagged AFTER MEAL



When the memory is full, the oldest result is erased as the newest is added.

Press ▼ to move backward and ▲ to move forward through your results. Pressing and holding ▲ or ▼ allows you to move more quickly.

To view details of an individual result, press ▲ or ▼ to highlight the result, then press OK. If you wish to add or change a meal flag or comment for this result, see Section 3, Attaching meal flags or comments to your test results.

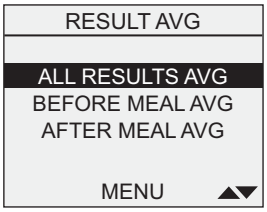
To return to the previous screen, press ↩.

To return to the MAIN MENU, highlight MENU, then press OK.

Result averages

The meter will display three types of averages:

- All test results
- Before-meal results
- After-meal results

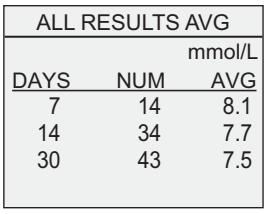


If the flags/comments feature is off, selecting RESULT AVG from the MAIN MENU will lead directly to the ALL RESULTS AVG screen.

To return to the MAIN MENU from the RESULT AVG screen, highlight MENU, then press OK.

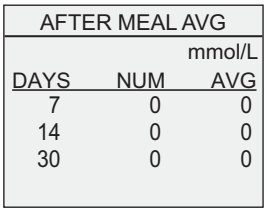
For each of the 7-, 14-, and 30-day periods leading up to the current date, the meter will display the number of results obtained (NUM) and the average of those results (AVG).

From any screen showing averages, press ↩ to go back to the previous screen.



If you do not have results in the past 7-, 14-, and 30-day periods, the NUM and AVG columns will show zero.

In result averages, a HI result is always counted as 33.3 mmol/L, and a LO result is always counted as 1.1 mmol/L. (See *Interpreting unexpected test results* in Section 2, for more information on high and low glucose results.)



The meter calculates averages based on the 7-, 14-, and 30-day periods ending on the current date setting. If you change your date setting, your averages may change too.

Result averages provide information from past results. **Do Not** use result averages to make immediate treatment decisions.

Downloading results to a computer

OneTouch® Diabetes Management Software (DMS) can store all of your records and help you spot patterns for planning meals, exercise, insulin dosing, and medication. For order information and to learn more about downloading data to a computer, visit www.OneTouch.com.au or contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.

To transfer meter data, follow the instructions provided with the OneTouch® DMS to download the results from the meter.

Once the command to start the download is sent from the computer to the meter, the meter display will show "PC" indicating that the meter is in communication mode.

⚠ WARNING: To avoid possible shock, Do Not insert a test strip while the meter is connected to a computer.

5 Control solution testing

When to test with control solution

OneTouch® Verio™ Control Solution is used to check that the meter and test strips are working together properly and that you are performing the test correctly. (Control solution is available separately.)

- Use only OneTouch® Verio™ Control Solution. Any level can be used to check your system.
- When you first open a new vial of control solution, record the discard date on the vial label. Refer to the control solution insert or vial label for instructions on determining the discard date.
- Make sure your meter, test strips, and control solution are at the same temperature before testing.
- Tightly close the cap on the control solution vial immediately after use to avoid contamination or damage.

> ⚠ **CAUTION:**
> - **Do Not** swallow or ingest control solution.
> - **Do Not** apply control solution to the skin or eyes as it may cause irritation.
> - **Do Not** use control solution after the expiration date (printed on the vial label) or the discard date, whichever comes first, or your results may be inaccurate.

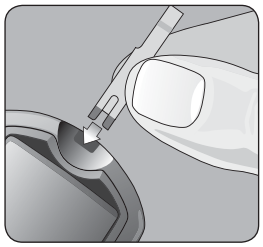
Do a control solution test

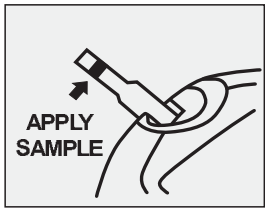
- Whenever you open a new vial of test strips.
- If you suspect that the meter or test strips are not working properly.
- If you have had repeated unexpected blood glucose results.
- If you drop or damage the meter.

How to test with control solution

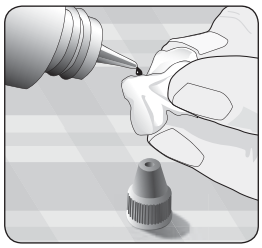
❶ Insert a test strip to turn the meter on

Wait for the APPLY SAMPLE screen to appear on the display.

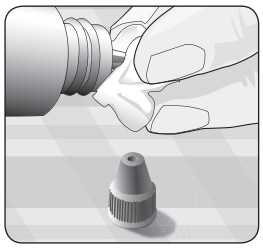


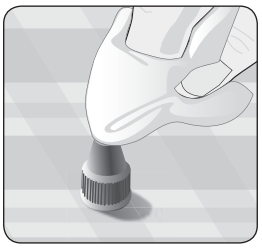


❷ Prepare the control solution



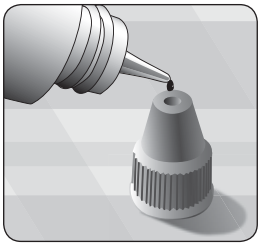
Remove the vial cap and place it on a flat surface with the top of the cap pointing up. Squeeze the vial to discard the first drop.





Wipe both the tip of the control solution vial and the top of the cap with a clean, damp tissue or cloth.

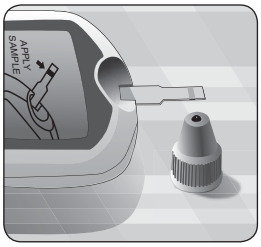
Then, squeeze a drop into the small well on the top of the cap or onto another clean, non-absorbent surface.

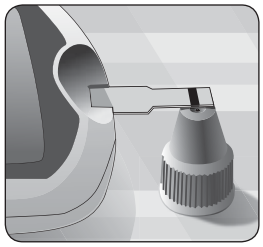


❸ Apply the control solution

Hold the meter so that the side edge of the test strip is at a slight angle to the drop of control solution.

Touch the channel on the side of the test strip to the control solution. Wait for the channel to fill completely.





❹ Read your result

The meter will count down from 5 to 1. Your result is displayed along with the date, time, unit of measure, and the words CONTROL SOLUTION.

The meter automatically marks the result as a control solution test.

> ⚠ **CAUTION:** If the words **CONTROL SOLUTION** do not appear on the screen, repeat the test with a new test strip. If the problem persists, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.
>
> ***NOTE:*** The result will be included in your averages and your averages will change too.

(Example)

❺ Check if the result is in range

Compare the result displayed on the meter to the range printed **on your OneTouch® Verio™ Control Solution vial**. If your control solution result falls outside the expected range, repeat the test with a new test strip.

❻ Cleaning

Clean the top of the control solution cap with a clean, damp tissue or cloth.

(Example range)

Out-of-range results may be due to:

- Not following the instructions detailed in Steps 1–5.
- Control solution is contaminated, expired, or past its discard date.
- Test strip or test strip vial is damaged, expired, or past its discard date.
- Meter, test strips and/or control solution were not all at the same temperature when the control solution test was performed.
- A problem with the meter.
- Dirt or contamination in the small well on the top of the control solution cap (see Step 2).

Control solution results can be seen when reviewing past results, but are not included in result averages.

> ⚠ **CAUTION:**
>
> - If you continue to get control solution test results that fall outside the range printed on the control solution vial, **Do Not** use the meter, test strips, or control solution. Contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.
> - Control solution ranges printed on control solution vials are for control solution tests only **and are not recommended ranges for your blood glucose level**.

6 Care and maintenance

Caring for your system

Storing your system
Store your meter, test strips, control solution and other items in your carrying case. Keep in a cool, dry place below 30°C, but **Do Not** refrigerate. Keep all items away from direct sunlight and heat.

Cleaning and caring for your meter
Wipe the outside with a soft cloth dampened with water and mild detergent.
- **Do Not** use alcohol or any other solvent.
- **Do Not** allow liquids, dirt, dust, blood, or control solution to enter the test strip port or the data port. (Refer to meter illustration in Section 1, Setting up your system.)
- **Do Not** spray cleaning solution on the meter or immerse it in any liquid.

NOTE: For health care professionals or caregivers who assist multiple users, to disinfect the meter, cleanse the meter using a 10% bleach solution (nine parts water, one part bleach).

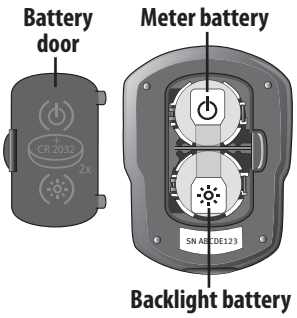
Cleaning your lancing device and clear cap
To clean these items, wipe them with a soft cloth dampened with water and mild detergent. **Do Not** immerse the lancing device in any liquid.

To disinfect these items, prepare a solution of one part household bleach to nine parts water. Wipe the lancing device with a soft cloth dampened with this solution. Immerse the **caps only** in this solution for 30 minutes. Rinse briefly with water and allow both to air dry.

Replacing the batteries

Your OneTouch® Verio™ Meter uses two 3.0 Volt CR 2032 lithium batteries. One battery powers the meter only and the other powers the backlight.

See *Troubleshooting* in Section 7, for information on when to change the **meter** battery. Replace the **backlight** battery when the backlight no longer comes on.



❶ Remove the old battery

Start with the meter turned off. Open the battery door and pull up firmly on the plastic battery tab. The plastic battery tab with the ⏻ symbol is for the meter battery, and the plastic tab with the ☼ symbol is for the backlight battery.

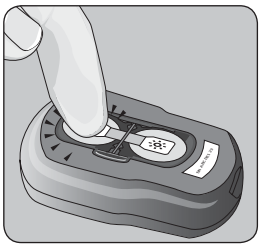
⚠ WARNING: To avoid a possible shock, Do Not change either battery while the meter is connected to a computer.

❷ Insert the new battery

With the "+" side facing up toward you, place the battery in the compartment within the fold of the plastic battery tab.

Push the battery until it snaps into the battery clasp.

Replace the battery door.



If the meter does not power on after you have replaced the meter battery, check that the battery is correctly installed with the "+" side up. If the meter still does not power on, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.

❸ Check your meter settings

Removing the meter battery will not affect your stored results. However, you may need to re-set your meter settings. (See *Setting the meter language, audio, date and time* in Section 1.)

❹ Dispose of batteries

Dispose of batteries according to your local environmental regulations.

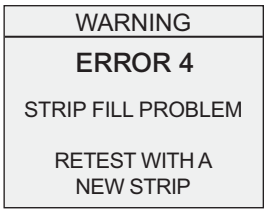
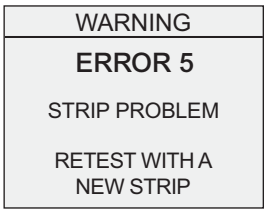
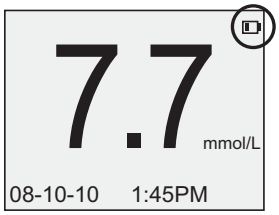
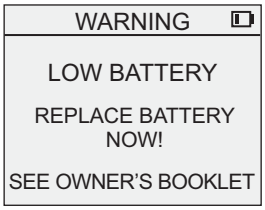
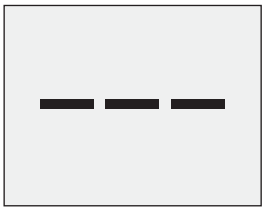
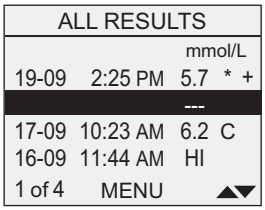
7 Troubleshooting and detailed information about your system

Troubleshooting

The OneTouch® Verio™ Meter displays messages when there are problems with the test strip, with the meter, or when your blood glucose levels are above 33.3 mmol/L or below 1.1 mmol/L. Improper use may cause an inaccurate result without producing an error message.

In this section, screens that display "SEE OWNER'S BOOKLET" mean you should refer to this User Guide.

Message	What it means	What to do
WARNING **LOW GLUCOSE** BELOW 1.1 mmol/L	You may have a very low blood glucose level (severe hypoglycaemia), below 1.1 mmol/L.	**This may require immediate treatment according to your health care professional's recommendations.** Although this message could be due to a test error, it is safer to treat first and then do another test.
WARNING **HIGH GLUCOSE** ABOVE 33.3 mmol/L	You may have a very high blood glucose level (severe hyperglycaemia), over 33.3 mmol/L.	**Re-test your blood glucose.** If the result is HIGH GLUCOSE again, obtain and follow instructions from your health care professional right away.
WARNING **TEMPERATURE ERROR** OUT OF OPERATING RANGE SEE OWNER'S BOOKLET	Meter is too hot (above 44°C) or too cold (below 6°C) to work correctly.	Move the meter and test strips to a cooler or warmer area. Insert a new test strip when the meter and test strips are within the operating range (6–44°C). If you do not get another TEMPERATURE ERROR message, you can proceed with testing.
WARNING **ERROR 1** METER PROBLEM CALL CUSTOMER SERVICE	There is a problem with the meter.	**Do Not** use the meter. Contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.
WARNING **ERROR 2** METER OR STRIP PROBLEM RETEST WITH A NEW STRIP	Error message could be caused either by a used test strip or a problem with the meter.	Repeat the test with a new test strip; see *Applying blood and reading results* in Section 2 or Section 5, Control solution testing. If this message continues to appear, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.
WARNING **ERROR 3** METER WAS NOT READY RETEST WITH A NEW STRIP	The sample was applied before the meter was ready.	Repeat the test with a new test strip. Apply a blood or control solution sample only after APPLY SAMPLE appears on the display. If this message continues to appear, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.

Message	What it means	What to do
	***One of the following may apply:*** • Not enough blood or control solution was applied or more was added after the meter began to count down. • The test strip may have been damaged or moved during testing. • The sample was improperly applied. • There may be a problem with the meter.	Repeat the test with a new test strip; see *Applying blood and reading results* in Section 2 or Section 5, Control solution testing. If the error message appears again, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.
	The meter has detected a problem with the test strip. Possible cause is test strip damage.	Repeat the test with a new test strip; see *Applying blood and reading results* in Section 2 or Section 5, Control solution testing. If the error message appears again, contact Customer Service: 1800-LifeScan. Customer Service is available from 8:00AM to 6:00PM, Monday - Friday.
	Meter battery is low but still has enough power to perform a test.	This symbol is displayed when the meter battery is low and will continue to appear until the battery is replaced. Test results will still be accurate but replace the battery as soon as possible; see *Replacing the batteries* in Section 6.
	Meter battery does not have enough power to perform a test. Meter may be too cold (below 6°C) to work correctly.	If this error is displayed while the meter is in the operating range (6–44°C), replace the meter battery immediately; see *Replacing the batteries* in Section 6. If this error is displayed when the meter is cold, move the meter and test strips to a warmer area and test again with a new test strip when the meter and test strips are within the operating range (6–44°C).
	No result in memory, such as the first time use of the meter. ***Or,*** Your meter was unable to recall this result. This result will not be included in result averages.	You can still perform a blood glucose test and get an accurate result. Contact Customer Service: 1800-LifeScan (Customer Service is available from 8:00AM to 6:00PM, Monday - Friday) to report this occurrence, **unless** this is your first use of the meter.
	Your meter was unable to recall this result. This result will not be included in result averages.	You can still perform a blood glucose test and get an accurate result, but contact Customer Service: 1800-LifeScan (Customer Service is available from 8:00AM to 6:00PM, Monday - Friday) to report this occurrence.

Detailed information about your system

Comparing meter results to laboratory results

Results obtained from the OneTouch® Verio™ Meter and laboratory tests are reported in plasma-equivalent units. However, your meter result may differ from your lab result due to normal variation. A result from your OneTouch® Verio™ Meter is considered accurate when it is within ±15% of the lab result.

Meter results can be affected by factors that do not affect lab results in the same way, which may cause a difference of more than ±15%. Specific factors that may cause your meter result to vary from your lab result by more than ±15% include:

- You have eaten recently. This can cause a result from fingertip testing to be up to 3.8 mmol/L higher than a lab test using blood drawn from a vein.[1]
- Your haematocrit is above 60% or below 20%.
- You are severely dehydrated.
- For additional information, refer to the OneTouch® Verio™ Test Strip Insert.

Guidelines for obtaining accurate meter to lab comparisons:

Before going to the lab:

- Perform a control solution test to make sure your meter is working properly.
- **Do Not** eat for at least 8 hours before you test your blood.
- Take your meter and testing supplies with you to the lab.

Testing with your OneTouch® Verio™ Meter at the lab:

- Test within 15 minutes of the lab test.
- Use only a fresh, capillary blood sample from your fingertip.
- Follow all instructions in this User Guide for performing a blood glucose test.

1. Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood E.R. (Ed.), *Tietz Textbook of Clinical Chemistry*, Philadelphia: W.B. Saunders Company (1994), 959.

Technical specifications

Reported result range	1.1–33.3 mmol/L
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample volume	0.4 µL
Test time	5 seconds
Assay method	GDH-FAD glucose dehydrogenase
Power source	Two 3.0 Volt CR 2032 lithium batteries
Expected meter battery life	Minimum six months at average of four tests per day
Unit of measure	mmol/L
Memory	500 test results
Automatic shutoff	Two minutes after last action
Size	74.7 mm x 55.5 mm x 19.9 mm
Weight	Approximately 52.6 grams, with batteries
Operating ranges	Temperature: 6–44°C Relative humidity: non-condensing 10–90% Altitude: up to 3048 meters Haematocrit: 20–60%
Battery ratings	2 x 3.0 V, ⎓ , 60 mA (2 x CR 2032 batteries) ⎓ direct current

Performance Characteristics

System Accuracy:

Diabetes experts have suggested that glucose meters should agree within 0.8 mmol/L of a laboratory method when the glucose concentration is lower than 4.2 mmol/L, and within 20% of a laboratory method when the glucose concentration is 4.2 mmol/L or higher. However, experts have suggested greater accuracy of Blood Glucose Monitoring Systems is desirable. The OneTouch® Verio™ Blood Glucose Monitoring System has demonstrated accuracy within ± 0.7 mmol/L of the laboratory method for glucose concentrations lower than 4.4 mmol/L, and within ±15% of the laboratory method for glucose concentrations 4.4 or higher. Samples from 100 patients were tested using both the OneTouch® Verio™ System and the YSI 2300 glucose analyser laboratory instrument.

System Accuracy Results for Glucose Concentrations <4.4 mmol/L
Percent (and number) of meter results that match the laboratory test

Within ±0.3 mmol/L	Within ±0.6 mmol/L	Within ±0.7 mmol/L	Within ±0.8 mmol/L
93/114 (81.6%)	110/114 (96.5%)	114/114 (100.0%)	114/114 (100.0%)

System Accuracy Results for Glucose Concentrations ≥4.4 mmol/L
Percent (and number) of meter results that match the laboratory test

Within ±5%	Within ±10%	Within ±15%	Within ±20%
303/486 (62.4%)	446/486 (91.8%)	481/486 (99.0%)	485/486 (99.8%)

The OneTouch® Verio™ System has demonstrated accuracy within ± 0.7 mmol/L of the laboratory method for glucose concentrations lower than 4.4 mmol/L, and within ±15% of the laboratory method for glucose concentrations 4.4 mmol/L or higher. Therefore, 99.2% of the total results obtained with the OneTouch® Verio™ System meets this higher accuracy specification and exceeds the goal suggested by diabetes experts.

System Accuracy Results across the entire Glucose Range
Percent (and number) of meter results that match the laboratory test

Within ±0.7 mmol/L or ±15%
595/600 (99.2%)

Regression Statistics
Samples were tested in duplicate on three test strip lots. Results indicate that the OneTouch® Verio™ System compares well with a laboratory method.

# of Subjects	# of Tests	Slope	Intercept (mmol/L)
100	600	0.994	-0.011

95% CI Slope	95% CI Intercept	Std. Error ($S_{y.x}$)	R^2
0.986 to 1.003	-0.109 to 0.087	0.641	0.988

Precision
Within Run Precision
(300 Venous Blood Tests)

Target Glucose (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of Variation (%)
2.2	2.19	0.06	2.72
5.6	5.59	0.10	1.74
7.2	7.01	0.13	1.91
11.0	10.51	0.19	1.78
19.4	17.98	0.37	2.05

Results show that the greatest variability observed between test strips when tested with blood is 2.72% or less.

Total Precision
(600 Control Solution Tests)

Glucose Level Ranges (mmol/L)	Mean Glucose (mmol/L)	Standard Deviation (mmol/L)	Coefficient of variation (%)
Low (2.11–3.44)	2.81	0.07	2.53
Mid (5.67–7.67)	6.47	0.16	2.48
High (16.56–22.39)	19.45	0.43	2.2

Electrical and safety standards

This meter complies with CISPR 11: 2003, Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment. The meter has been tested for immunity to Level 3 electrostatic discharge as specified in IEC 61000-4-2. This meter has been tested for immunity to radio frequency interference over the frequency range 80 MHz to 2.5 GHz at 3 V/m as specified in IEC 61000-4-3.

Lifetime Warranty

By completing and returning the warranty application enclosed you can become a member of the Johnson & Johnson Medical (JJM) Pty Ltd OneTouch® Verio™ Program. This membership provides you with the OneTouch® Verio™ warranty by JJM, which covers you for both the blood glucose meter you have just purchased and any replacement meter you receive from JJM in the future.

The OneTouch® Verio™ warranty covers any defects in material or workmanship, whenever appearing, but does not apply to battery defects, accidental damage, normal wear and tear, or if the meter is misused.